(4) Aluminum phosphate gel when used as part of an antacid combination product and contributing at least 25 percent of the total acid neutralizing capacity; maximum daily dosage limit is 8 grams.

(5) Dihydroxyaluminum sodium carbonate.

(b) Bicarbonate-containing active ingredients: Bicarbonate ion; maximum daily dosage limit 200 mEq.; for persons up to 60 years old and 100 mEq. for persons 60 years or older.

(c) Bismuth-containing active ingredients:
   (1) Bismuth aluminate.
   (2) Bismuth carbonate.
   (3) Bismuth subcarbonate.
   (4) Bismuth subgallate.
   (5) Bismuth subnitrate.

(d) Calcium-containing active ingredients: Calcium, as carbonate or phosphate; maximum daily dosage limit 160 mEq. of calcium (e.g., 8 grams calcium carbonate).

(e) Citrate-containing active ingredients: Citrate ion, as citric acid or salt; maximum daily dosage limit 8 grams.

(f) Glycine (aminoacetic acid).

(g) Magnesium-containing active ingredients:
   (1) Hydrate magnesium aluminate activated sulfate.
   (2) Magaldrate.
   (3) Magnesium aluminosilicates.
   (4) Magnesium carbonate.
   (5) Magnesium glycinate.
   (6) Magnesium hydroxide.
   (7) Magnesium oxide.
   (8) Magnesium trisilicate.
   (h) Milk solids, dried.
   (i) Phosphate-containing active ingredients:
      (1) Aluminum phosphate; maximum daily dosage limit 8 grams.
      (2) Mono or dibasic calcium salt; maximum daily dosage limit 2 grams.
      (3) Tricalcium phosphate; maximum daily dosage limit 24 grams.
   (j) Potassium-containing active ingredients:
      (1) Potassium bicarbonate (or carbonate when used as a component of an effervescent preparation); maximum daily dosage limit 200 mEq. of bicarbonate ion for persons up to 60 years old and 100 mEq. of bicarbonate ion for persons 60 years or older.
      (2) Sodium potassium tartrate.

(k) Sodium-containing active ingredients:
   (1) Sodium bicarbonate (or carbonate when used as a component of an effervescent preparation); maximum daily dosage limit 200 mEq. of sodium for persons up to 60 years old and 100 mEq. of sodium for persons 60 years or older, and 100 mEq. of bicarbonate ion for persons 60 years or older. That part of the warning required by §330.1(g), which states, “Keep this and all drugs out of the reach of children” is not required on a product which contains only sodium bicarbonate powder and which is intended primarily for other than drug uses.
   (2) Sodium potassium tartrate.
   (l) Silicates:
      (1) Magnesium aluminosilicates.
      (2) Magnesium trisilicate.
   (m) Tartrate-containing active ingredients. Tartaric acid or its salts; maximum daily dosage limit 200 mEq. (15 grams) of tartrate.


§ 331.15 Combination with nonantacid active ingredients.

(a) An antacid may contain any generally recognized as safe and effective nonantacid laxative ingredient to correct for constipation caused by the antacid. No labeling claim of the laxative effect may be used for such a product.

(b) An antacid may contain any generally recognized as safe and effective analgesic ingredient(s), if it is indicated for use solely for the concurrent symptoms involved, e.g., headache and acid indigestion, and is marketed in a form intended for ingestion as a solution.

(c) An antacid may contain any generally recognized as safe and effective antiflatulent ingredient if it is indicated for use solely for the concurrent symptoms of gas associated with heartburn, sour stomach or acid indigestion.

Subpart C—Testing Procedures

§ 331.20 Determination of percent contribution of active ingredients.

To determine the percent contribution of an antacid active ingredient,
place an accurately weighed amount of
the antacid active ingredient equal to
the amount present in a unit dose of
the product into a 250-milliliter (mL)
beaker. If wetting is desired, add not
more than 5 mL of alcohol (neutralized
to an apparent pH of 3.5), and mix to
wet the sample thoroughly. Add 70 mL
of water, and mix on a magnetic stirrer
at 300 ± 30 r.p.m. for 1 minute. Analyze
the acid neutralizing capacity of the
sample according to the procedure pro-
vided in the United States Pharma-
copia 23/National Formulary 18 and
calculate the percent contribution of
the antacid active ingredient in the
total product as follows:
Percent contribution =
(Total mEq.
Antacid Active Ingredient×100)/(Total
mEq. Antacid Product).
[61 FR 4823, Feb. 8, 1996]

§ 331.21 Test modifications.
The formulation or mode of adminis-
tration of certain products may require
a modification of the United States
Pharmacopeia 23/National Formulary
18 acid neutralizing capacity test. Any
proposed modification and the data to
support it shall be submitted as a peti-
tion under the rules established in
§10.30 of this chapter. All information
submitted will be subject to the disclo-
sure rules in part 20 of this chapter.
[61 FR 4823, Feb. 8, 1996]

Subpart D—Labeling

§ 331.30 Labeling of antacid products.

(a) Statement of identity. The labeling
of the product contains the established
name of the drug, if any, and identifies
the product as an “antacid.”

(b) Indications. The labeling of the
product states, under the heading “In-
dications,” the following: “For the re-
lief of” (optional, any or all of the fol-
lowing:) “heartburn,” “sour stomach,”
and/or “acid indigestion” (which may
be followed by the optional statement):“and upset stomach associated with”
(optional, as appropriate)”this symp-
tom” or “these symptoms.” Other
truthful and nonmisleading state-
ments, describing only the indications
for use that have been established and
listed in this paragraph (b), may also
be used, as provided in §330.1(c)(2) of
this chapter, subject to the provisions of
section 502 of the act relating to
misbranding and the prohibition in sec-
tion 301(d) of the act against the intro-
duction or delivery for introduction
into interstate commerce of unap-
proved new drugs in violation of sec-
tion 505(a) of the act.

(c) Warnings. The labeling of the
product contains the following warn-
ings, under the heading “Warnings”,
which may be combined but not rear-
ranged to eliminate duplicative words
or phrases if the resulting warning is
clear and understandable:
(1) “Do not take more than (max-
imum recommended daily dosage, bro-
ken down by age groups if appropriate,
expressed in units such as tablets or
tea spoonfuls) in a 24-hour period, or
use the maximum dosage of this prod-
uct for more than 2 weeks, except
under the advice and supervision of a
physician.”

(2) For products which cause con-
stipation in 5 percent or more of per-
sons who take the maximum rec-
ommended dosage: “May cause con-
stipation.”

(3) For products which cause laxation
in 5 percent or more of persons who
take the maximum recommended dos-
age: “May have laxative effect.”

(4) For products containing more
than 5 gm per day lactose in a max-
imum daily dosage: “Do not use this
product except under advice and super-
vision of a physician if you are allergic
to milk or milk products.”

(d) Drug interaction precaution. The
labeling of the product contains the
following statement “Ask a doctor or
pharmacist before use if you are [bul-
let]1 presently taking a prescription
drug. Antacids may interact with cer-
tain prescription drugs.”

(e) Directions for use. The labeling of
the product contains the recommended
dosage, under the heading “Direc-
tions”, per time interval (e.g., every 4
hours) or time period (e.g., 4 times a
day) broken down by age groups if ap-
propriate, followed by “or as directed
by a physician.”

(f) Exemption from the general acci-
dental overdose warning. The labeling
for antacid drug products containing

1 See §201.66(b)(4) of this chapter.